CORRECTED

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0980V

UNPUBLISHED

KIMBERLY AXELROD, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: October 25, 2022 Special Processing Unit (SPU); Ruling on Entitlement; Findings of Fact; Severity; Site of Vaccination; Onset; Influenza (Flu); Shoulder Injury Related to Vaccine Administration (SIRVA).

LeeAnne Pedrick, Maglio, Christopher, & Toale PA, Washington, DC, for Petitioner.

Nina Ren, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On February 22, 2021, Kimberly Axelrod filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that as a result of receiving the influenza ("flu") vaccine on September 22, 2020, she suffered a left-sided shoulder injury related to vaccine administration ("SIRVA") as defined on the Vaccine Injury Table (the "Table"). Petition (ECF No. 1) at Preamble. The case was assigned to the Special Processing Unit ("SPU") of the Office of Special Masters.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the reasons discussed below, I find that the flu vaccine was most likely administered in Petitioner's left arm; her injury persisted for more than six months; and onset occurred within 48 hours.

I. Relevant Procedural History

Three months after the case's imitation, Ms. Axelrod filed medical records, a declaration,[3] and other materials needed to evaluate what records should be filed to substantiate the claim (Exs. 1-22). On October 20, 2021, I deemed the record complete pursuant to Section 11(c) of the Vaccine Act. However, I noted a discrepancy between Petitioner's allegations and one contemporaneous record indicating a right-sided vaccine administration (Ex. 12 at 5, 7, 9). PAR Activation Order (ECF No. 13). On January 3, 2022, Petitioner filed an Amended Petition (ECF No. 18), as well as some supplemental declarations (Exs. 23-24).

On March 7, 2022, Respondent offered his preliminary review and analysis of the case. Status Report (ECF No. 23). Petitioner then filed supplemental contemporaneous evidence (Ex. 25) and her original declaration unchanged except for a new signature dated May 19, 2022 (Ex. 26).

On May 31, 2022, the parties were permitted to file any additional evidence and briefing on the factual and/or legal issues raised by Respondent, and receive my resolution thereof, while the case awaited Respondent's medical review. Scheduling Order (ECF No. 30). Petitioner was granted additional time. Motion (ECF No. 31); Order (ECF No. 32); Exs. 27-28. Thereafter on September 1, 2022, Petitioner filed a Motion for Findings of Fact ("Motion") (ECF No. 39).[4] On September 15, 2022, Respondent filed his Response in opposition (ECF No. 40). On September 28, 2022, Petitioner filed a Reply (ECF No. 41). I have determined that resolution of several disputed fact issues is appropriate and will assist in the case's ultimate resolution.[5]

[3] In each statement submitted to date, the witness declared that his or her statements are true and correct under penalty of perjury. *See* 28 U.S.C. § 1746 (providing that such a statement shall carry "like force and effect" as a notarized affidavit).

[4] Also on September 1, 2022, Petitioner reported that she was no longer undergoing formal treatment for her shoulder as her pain had mostly subsided, and that she had not yet conveyed a demand to Respondent in light of the identified factual issues. ECF No. 38.

[5] *See also* Response at 3 and n. 1-2 (providing that Respondent had not conducted the required medical analysis of the claim as of September 15, 2022, and estimating that would occur in December 2022).

II. Applicable Legal Standard

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health*

& Hum. Servs., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

III. Relevant Evidence

I have reviewed all of the evidence filed to date. This ruling, however, is limited to determining facts pertaining to disputed factual issues. Accordingly, I will offer only a limited summary of the relevant facts. Specifically:

- Petitioner was thirty-seven (37) years old with a non-contributory medical history. She received a flu vaccine in October 2018 in her left arm. Ex. 12 at 12. She received another flu vaccine in October 2019, but the site is not recorded. Ex. 13 at 10. She is right-handed. *Id.*

- On September 22, 2020, at approximately 8:00 a.m., Petitioner presented to the Commonwealth Medical Center Urgent Care ("CMC Urgent Care") clinic in Arlington, Virginia. *See* Ex. 12 at 7-9. Petitioner sought 1) COVID-19 testing that was required before a surgical procedure and 2) the subject flu vaccination. Ex. 12 at 8.[6] She reported no complaints. *Id.* Her temperature, pulse, and oxygen level were normal. *Id.* at 7. She "stated" her weight and height. *Id.* Physical exam of the eyes, as well as the constitutional, respiratory, and cardiovascular systems, was unremarkable. *Id.* at 8. A rapid antigen test for COVID-19 was negative. *Id.* at 9. She was instructed on "the need to continue with protective measures and social distance, mask wearing, etc." *Id.*

[6] *See also* Ex. 13 at 26-28 (September 9, 2020, orthopedics pre-operative consultation regarding surgery on her foot).

- During the same CFC urgent care encounter, Petitioner also received the subject vaccine. The record reflects: "Site: Arm, Right Upper." Ex. 12 at 7, 9. Yukeenia Malcolm is listed as the "vaccinator." *Id.* at 7. However, a physician assistant ("PA"), Alison Broadbent, is listed as the provider and signed off on the resulting records. *Id.*

- A separate "Data Portability" record reflects receipt of the subject vaccine, but no site. Ex. 1 at 3. This record is uncertified, and its origin is unclear. *See also* Exhibit List (ECF No. 36-1) (identifying Ex. 1 only as "Vaccination Record").

- On September 24, 2020, Petitioner underwent surgery on her left foot with local sedation. Ex. 13 at 52. Later that day, the orthopedic surgeon telephoned Petitioner, answered unspecified questions, and encouraged her to call back as needed. *Id.* at 30. Petitioner was prescribed aspirin, promethazine, and Percocet (oxycodone-acetaminophen) for her post-operative foot pain. *Id.*

- No circumstances about the vaccination or the condition of Petitioner's left shoulder are reflected in the records of:

    - An October 2, 2020, primary care appointment conducted via telemedicine. Ex. 10 at 7-8. At this appointment, Petitioner's chief complaint was chills, for which the PA could not rule out COVID-19. *Id.* at 8.

    - October 2, 2020, and October 24, 2020, orthopedics appointments following up on her recent foot surgery. Ex. 13 at 32-34, 35-37. At each encounter, the current medications list reflected aspirin for pain. *Id.* at 32, 35. On physical exam, review of the musculoskeletal system was limited to the lower extremities. Ex. 13 at 34, 37.[7]

[7] It is also observed that within each orthopedics record (dating from December 2019 – February 2021, including the specific records noted above), the "Review of Systems" section is positive only for "Musculoskeletal: Back Pain." *See* Ex. 13 at 9, 13, 17, 22, 26, 32, 35, 38, 40, 43, 45, 47, 49. It is likely that the orthopedist did not utilize this section of the record, relying instead on the "chief complaint" and "HPI" [history of present illness] sections.

- October 13, 2020, and October 22, 2020, chiropractic "routine maintenance appointments" for established chief complaints of pain in her neck, back, hip, and bilateral trapezius muscles. Ex. 28 at 13-14.

- Thirty-seven (37) days after vaccination, on October 29, 2020, Petitioner attended another primary care appointment via telemedicine. Ex. 10 at 7. The PA recorded that Petitioner "got flu shot 5 weeks ago, initially just felt sore; since then has sharp pain in left shoulder region," despite dry needling from a chiropractor. *Id.* The PA did not address the shoulder in the (telemedicine) exam, was unsure if the pain was "related to recent injection," and recorded that Petitioner would see her established orthopedist. *Id.*

- On November 3, 2020, Petitioner presented to her established orthopedist, reporting that since her flu shot five weeks ago, she developed worsening pain when doing certain movements with her left shoulder. Ex. 13 at 38. She reported that the "usual" pain rated at 5/10, it was qualitatively "moderate," and it improved with rest. *Id.* On physical exam of the left shoulder, active range of motion ("AROM") was painful at the end ranges. *Id.* at 39. Hawk in's and Neer's tests were positive and elicited pain. *Id.* The orthopedist assessed left shoulder impingement syndrome and bursitis, for which he prescribed Voltaren (diclofenac sodium extended-release tablets) and recommended a course of physical therapy. *Id.*

- Petitioner subsequently saw various medical providers for left shoulder pain, which she consistently related back to the flu vaccine. *See, e.g.*, Ex. 4 (first PT course from November 11 – 24, 2020); Ex. 9 (first PT course from December 16, 2020 – January 26, 2021); Ex. 4 at 8 (February 2, 2021, orthopedics encounter and steroid injection); Ex. 9 at 47-49 (PT encounter documenting "no pain" but continued muscle tightness); Ex. 15 (March 17, and March 27, 2021 PT sessions – representing the last formal medical treatment in evidence, just over six months after vaccination).

- Petitioner submitted an archived version of CMC Urgent Care's webpage as of September 2020, which reflects that the facility was "doing almost exclusively [COVID-19] testing and… working to accommodate a large volume of patients."

Ex. 25[8] at 2. A patient seeking COVID-19 testing should "drive in and pull up facing the Urgent Care," call to report his or her arrival, and wait outside for any needed paperwork and for the encounter, which would begin with vitals and the COVID-19 test via nasal swab. *Id.* Afterwards, the provider on duty would come out, complete an evaluation, and discuss the test results. *Id.* at 3-4. CMC Urgent Care was continuing to offer other urgent care services including STD testing and x-rays. *Id.* at 5-6. The webpage does not address the availability or administration procedures for vaccines.

- In a declaration dated January 3, 2022, Petitioner recalled that on September 22, 2020, she had presented to CMC Urgent Care for the purpose of testing for COVID-19. Ex. 23 at ¶¶ 1-2 4. Her husband had to work, so she drove herself to the appointment, which was set up as a "drive-through testing center." *Id.* at ¶ 3. Petitioner avers that she remained in her car, in the driver's seat, during the COVID-19 test and the flu shot. *Id.* at ¶ 6. This meant that both procedures were administered through the driver's side window, on her left-hand side, and that the flu shot was administered in her left shoulder. *Id.* at ¶¶ 6-7.

- Petitioner's husband, Andrew Axelrod, also offered a declaration dated January 3, 2022. He recalls that on September 22, 2020, he went to work rather than transporting or otherwise accompanying Petitioner to CMC Urgent Care. Ex. 24 at ¶ 3. That evening, Petitioner described the encounter – including receiving the COVID-19 test, as well as her flu vaccine in her left arm, while remaining in her car. *Id.* at ¶ 4. He recalls that from that evening forward, Petitioner began complaining about her left shoulder and that she began having unusual pain and soreness shortly after the vaccination was given. *Id.* at ¶ 5.

IV. Analysis

A. Severity

In his preliminary review and analysis, Respondent identified a potential issue regarding the statutory severity requirement. ECF No. 23, at 2, citing Section

[8] The archived webpage is publicly available via "The Wayback Machine." *See* Ex. 25 at 1 (citing https://web.archive.org/web/20200902194902/https://www.urgentcarearlingtonva.com/). Petitioner accessed the webpage as of September 2, 2020. Upon review, there were no relevant changes to the webpage before it was next archived on October 2, 2020.

11(c)(1)(D)(i). While the parties opted not to brief severity, it is a threshold requirement for eligibility under the Program. *Black v. Sec'y of Health & Hum. Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted). Thus, I will address it first.

Respondent noted that Petitioner's declaration attesting to the severity requirement is dated February 22, 2021 – which was only five months post-vaccination. Status Report (ECF No. 23) at 2, citing Ex. 3 (ECF No. 8-4). While Respondent's point is accurate, the petition stated that Petitioner "continue[d] to suffer from SIRVA, and "ha[d] an injury *which is being treated and will more likely than not require more than six months* of treatment." Petition (ECF No. 1) at ¶¶ 6, 8 (emphasis added). The circumstances in which the Petition was filed are relevant – for at that time there was widespread concern that SIRVA claims were to be eliminated from the Vaccine Injury Table. *Id.* at n. 1; *see also* 85 FR 43794-01 (July 20, 2020, notice of proposed rulemaking); 86 FR 6249 (final rule issued January 21, 2021, providing effective date of February 22, 2021); 86 FR 9308-01 (Feb. 12, 2021 (notice delaying effective date until April 23, 2021). I am not inclined to find that this error detracts from Petitioner's credibility, *see* Response at n. 4, but it may warrant some adjustment of her counsel's associated attorneys' fees and costs.

The medical records otherwise reflect that Petitioner sought regular medical care for her left shoulder leading up to a February 2, 2021, subacromial steroid injection. Ex. 13 at 49-51. Seven days later at physical therapy, she reported no pain but "continue[d] to demonstrate [muscular] tightness"; she was instructed to continue home exercises and avoid strenuous activity. Ex. 9 at 47-48. Following an approximately one-month gap in treatment, she reported that the cortisone shot "helped but [was] wearing off," and she was documented to have left shoulder pain (rated at 1-3/10) and objective limitations by a new therapist on March 17 and March 27, 2021. *See generally* Ex. 15.

The filed evidence thus documents a shoulder injury lasting just over "6 months after the administration of the vaccine," even if Petitioner could not establish severity at the date of the case's initiation. (This same evidence also, however, documents a mild SIRVA – something relevant to any damages to be awarded in this case.)

B. Situs

The parties primarily dispute whether Petitioner received the subject flu vaccine in her left arm as alleged, rather than in her right arm as documented on the contemporaneous medical records. Ex. 12 at 7, 9.

Medical records that are contemporaneous, clear, and consistent on a specific factual issue are presumed to be reliable, and therefore usually accorded more weight than later statements. Ms. Axelrod argues that this proposition does not apply in her case because of the "Data Portability" record. Reply at 5 (citing Ex. 1 at 3). However, this record is not clearly contemporaneous,[9] and it *omits* the key fact of situs, rather than *conflicting* with the CMC Urgent Care record on that point.

CMC Urgent Care created the single most contemporaneous medical record on the disputed fact of situs – and it clearly points towards a finding of the right upper arm. Response at 7 (citing Ex. 12 at 7-9). However, this record is not as persuasive as the evidence in the prior case cited by Respondent. Response at 7, citing *Schmidt v. Sec'y of Health & Human Servs.*, No. 17-1530V, 2021 WL 5226494 (Fed. Cl. Spec. Mstr. Oct. 7, 2021). In *Schmidt*, upon declining to favor the petitioner's later statements regarding situs, I noted that the vaccine administration record was "completed by hand… signed by both the vaccine administer and Petitioner… is consistent with the notes in [Mr. Schmidt's] electronic medical record [and…contains signatures from multiple vaccine administrators, suggesting that the site of injection is not recorded in advance and requiring thought on the part of the administrator." *Schmidt*, 2021 WL 5226494, at *8. Mr. Schmidt did not successfully challenge the reliability of the subject medical record, and moreover, it was consistent with other records of earlier vaccinations. *Id.* at *8-9.

Here, by contrast, there is only one record indicating situs. This record was electronic and most likely involved a prepopulated form (based on my experience reviewing such records in deciding other SIRVA claims). It was also not signed by Petitioner. The record does not indicate final approval by either the "vaccinator" or by Petitioner herself.

[9] Based on its heading and its contents, this record may instead represent a "snapshot" of the medical history, for Petitioner to present to new providers.

Moreover, Petitioner has introduced a credible, specific reason to doubt the reliability of the relevant medical record. CMC Urgent Care's webpage from the time in question reflects special procedures to facilitate an increased volume of patients and a focus on COVID-19 testing. *See generally* Ex. 25. The webpage does not expressly state that a patient must remain in his or her vehicle – but that would be feasible for the procedures involved (temperature, pulse, oxygen, a limited physical exam, and a nasal swab), as Petitioner has argued. Reply at 8. While CMC Urgent Care was offering certain other procedures that would necessitate exiting the vehicle (e.g., x-rays), it was "doing almost exclusively COVID-19 testing." Ex. 25 at 2. Petitioner's own primary purpose was to obtain COVID-19 testing; receipt of the flu vaccine appears to have been a secondary issue. Ex. 12 at 8. I find that the vaccine's administration also would have been feasible with Petitioner remaining in the driver's seat of her car, exposing her left shoulder. That would be consistent with Petitioner's previous receipt of at least one prior vaccine in her non-dominant left arm.

In addition, I accord some weight to the medical records in which Petitioner reported that her recent vaccination caused her left shoulder pain – as "information supplied to…. health professionals" intended to facilitate diagnosis and treatment. *Cucuras*, 993 F.2d at 1528. And Petitioner has provided additional support by way of a fact witness's affidavit. Thus, upon consideration of all the available evidence, I find that the September 22, 2020, flu vaccine was more likely administered in Ms. Axelrod's left arm, as alleged.

C. Onset

In his preliminary review and analysis, Respondent maintained that "the record does not support" onset occurring within 48 hours after vaccination. Status Report (ECF No. 23) at 2 and n. 1. Despite my invitation for briefing on any factual or legal issue raised by Respondent, this was not addressed in the Motion or Response, only the Reply – which does not address the cited physical therapy records. I will therefore review the record as a whole.

I recognize that the first post-vaccination medical records do not contain any information about the subject vaccination or Petitioner's left shoulder injury. However, those encounters were focused on other concerns, and some were inherently limited by the telemedicine context. Additionally, those encounters were within approximately the first month after vaccination – a period during which individuals often believe that they are experiencing routine post-vaccination pain which will self-resolve.

Once Petitioner began to seek medical treatment for her shoulder injury, however, she consistently faulted the vaccination. She first placed onset as generally "since" the vaccination occurring five weeks earlier. Ex. 10 at 7; Ex. 13 at 38. Respondent only identifies that the November 11, 2020, PT initial evaluation lists onset as "9/28/20." Ex. 4 at 18. This date may have been generated from Petitioner's history that "*about* 6 weeks ago had a flu shot and ended up with bursitis." *Id.* (emphasis added). However, the vaccine was in fact administered seven weeks plus a day before the PT initial evaluation. Thus, the recorded history is internally inconsistent – too much so to give it much weight either way. A preponderance of the evidence ultimately supports onset as likely having occurred within 48 hours of vaccination.

V. Conclusion and Scheduling Order

Based on recent data about the general processing times for SIRVA claims in general, I expect that Respondent will complete his medical review and form his tentative position in this case in approximately November 2022. I have not received both parties' positions, and thus have yet to formally consider whether Petitioner's injury meets all criteria for a Table SIRVA. However, in the light of the above findings and my preliminary review of the evidence overall, Petitioner shall proceed with preparing a demand for Respondent's consideration if she has not already done so. I understand that Respondent cannot provide a response to this demand until he has formulated his position. However, the parties should strive to be in a position to immediately discuss damages once Respondent indicates he is amenable to consideration of Petitioner's demand after Respondent's review is complete. In addition, it is sensible for Petitioner to calculate the likely damages as quickly as possible in any case pending in SPU.

Accordingly:

- **By no later than Tuesday, November 8, 2022, Petitioner shall file a status report indicating the date by which she conveyed or intends to convey a demand to Respondent.**

- **By no later than Monday, November 28, 2022, Respondent shall file a status report** updating on his **tentative position.** If Respondent intends to either concede or explore informal resolution of the case, the status report shall reflect the date by which Respondent responded, or intends to respond, any demand received from Petitioner. If Respondent wishes to file his report pursuant to Vaccine Rule 4(c), the status report shall propose a deadline for doing so.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master